READ IT BEFORE YOUR PATIENTS

Palliation

Palliative radiotherapy after oesophageal cancer stenting (ROCS): a multicentre, open-label, phase III randomised controlled trial.

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BACKGROUND

Patients with advanced oesophageal cancer have a median survival of 3-6 months, and most require intervention for dysphagia. Self-expanding metal stent (SEMS) insertion is the most typical form of palliation in these patients, but dysphagia deterioration and re-intervention are common. This study examined the efficacy of adjuvant external beam radiotherapy (EBRT) compared with usual care alone in preventing dysphagia deterioration and reducing service use after SEMS insertion.

METHODS

This was a multicentre, open-label, phase III randomised controlled trial based at cancer centres and acute care hospitals in England, Scotland, and Wales. Patients (aged ≥16 years) with incurable oesophageal carcinoma receiving stent insertion for primary management of dysphagia were randomly assigned (1:1) to receive usual care alone or EBRT (20 Gy in five fractions or 30 Gy in ten fractions) plus usual care after stent insertion. Usual care was implemented according to need as identified by the local multidisciplinary team (MDT). Randomisation was via the method of minimisation stratified by treating centre, stage at diagnosis (I-III vs IV), histology (squamous or non-squamous), and MDT intent to give chemotherapy (yes vs no). The primary outcome was difference in proportions of participants with dysphagia deterioration (>11 point decrease on patient-reported European Organisation for Research and Treatment of Cancer quality of life questionnaire-oesophagogastric module [QLQ-OG25], or a dysphagia-related event consistent with such a deterioration) or death by 12 weeks in a modified intention-to-treat (ITT) population, which excluded patients who did not have a stent inserted and those without a baseline QLQ-OG25 assessment. Secondary outcomes included survival, quality of life (QoL), morbidities (including time to first bleeding event or hospital admission for bleeding event and first dysphagia-related stent complications or re-intervention), and cost-effectiveness. Safety analysis was undertaken in the modified ITT population. The study is registered with the International Standard Randomised Controlled Trial registry, ISRCTN12376468, and ClinicalTrials.gov, NCT01915693, and is completed.

FINDINGS

220 patients were randomly assigned between 16 Dec 2013, and 24 Aug 2018, from 23 UK centres. The modified ITT population (n=199) comprised 102 patients in the usual care group and 97 patients in the EBRT group. Radiotherapy did not reduce dysphagia deterioration, which was reported in 36 (49%) of 74 patients receiving usual care versus 34 (45%) of 75 receiving EBRT (adjusted odds ratio 0·82 [95% CI 0·40-1·68], p=0·59) in those with complete data for the primary endpoint. No significant difference was observed in overall survival: median overall survival was 19·7 weeks (95% CI 14·4-27·7) with usual care and 18·9 weeks (14·7-25·6) with EBRT (adjusted hazard ratio 1·06 [95% CI 0·78-1·45], p=0·70; n=199). Median time to first bleeding event or hospital admission for a bleeding event was 49·0 weeks (95% CI 33·3-not reached) with usual care versus 65·9 weeks (52·7-not reached) with EBRT (adjusted subhazard ratio 0·52 [95% CI 0·28-0·97], p=0·038; n=199). No time versus treatment interaction was observed for prespecified QoL outcomes. We found no evidence of differences between trial group in time to first stent complication or re-intervention event. The most common (grade 3-4) adverse event was fatigue, reported in 19 (19%) of 102 patients receiving usual care alone and 22 (23%) of 97 receiving EBRT. On cost-utility analysis, EBRT was more expensive and less efficacious than usual care.

INTERPRETATION

Patients with advanced oesophageal cancer having SEMS insertion for the primary management of their dysphagia did not gain additional benefit from concurrent palliative radiotherapy and it should not be routinely offered. For a minority of patients clinically considered to be at high risk of tumour bleeding, concurrent palliative radiotherapy might reduce bleeding risk and the need for associated interventions.